

Attorney Docket # 4910-2DIV2

Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Divisional Application of

Steve ROFFLER et al.

Parent Serial No.: 09/810,379

Parent Filed: March 16, 2001

For: Monoclonal-Antibody for Analysis and
Clearance of Polyethylene Glycol and
Polyethylene Glycol-Modified Molecules

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SIR:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the documents listed on the enclosed Form PTO 1449. Copies of the listed documents are also enclosed.

In accordance with 37 C.F.R §§1.97(g) and (h), the filing of this Information Disclosure Statement should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56(b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant(s) reserve(s) the right to prove that the date of publication is in fact different.

If any fees or charges are deemed required at this time in connection with the application, the same may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

It is respectfully requested that the above information be considered by the Examiner and that the copy of the enclosed Form PTO-1449 be returned indicating that such information has been considered.

Respectfully submitted,
COHEN, PONTANI, LIEBERMAN & PAVANE

By Kent H. Cheng
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Dated: July 15, 2003

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		Application Number	
		Filing Date	
		First Named Inventor	Steve ROFFLER
		Art Unit	1642
		Examiner Name	S. Ungar
Sheet 1 of 2	Attorney Docket No.	4910-2DIV2	

U.S. PATENT DOCUMENTS

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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Klibanov et al., "Blood Clearance of Radiolabeled Antibody: Enhancement by Lactosamination and Treatment with Biotin-Avidin or Anti-Mouse IgG Antibodies", pp. 1951-1956, <u>The Journal of Nuclear Medicine</u> , Vol. 29, No. 12, Dec. 1988.	
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		Guermant et al., "Quantitative Determination of Polyethylene Glycol Based Upon Its Salting Out and Partitioning of a Dye into the Resulting Aqueous Two-Phase System", pp. 254-258, <u>Analytical Biochemistry</u> 230, (1995).	
		Kerr et al., "Application of Monoclonal Antibodies Against Cytosine Deaminase for the In Vivo Clearance of a Cytosine Deaminase Immunoconjugate", pp. 353-357, <u>Bioconjugate Chem.</u> , Vol. 4, No. 5, (1999).	
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		Kinahan et al., "High-Performance Liquid Chromatographic Determination of PEG 600 in Human Urine", pp. 297-307, <u>Journal of Chromatography</u> , 565, (1991).	
		Ruddy et al., "High-Performance Liquid Chromatographic Method for the Simultaneous Determination of Low-Molecular-Mass Oligomers of Polyethylene Glycol in Aqueous Skin Extracts", pp. 83-92, <u>Journal of Chromatography B</u> , 657 (1994).	
		Kobabayashi et al., "Comparison of the Chase Effects of Avidin, Streptavidin, Neutravidin, and Avidin-Ferritin on a Radiolabeled Biotinylated Anti-Tumor Monoclonal Antibody", pp. 310-314, <u>Jpn. J. Cancer Res.</u> , 86, March 1995.	
		Zhang et al., "Intravenous Avidin Chase Improved Localization of Radiolabeled Streptavidin in Intraperitoneal Xenograft Pretargeted With Biotinylated Antibody", pp. 61-64, <u>Nuclear Medicine & Biology</u> , Vol. 24 (1997).	
		Sharkey et al., "Second Antibody Clearance of Radiolabeled Antibody in Cancer Radioimmunodetection", pp. 2843-2846, <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 81, May 1985.	
		Nag et al., "A Colorimetric Assay for Estimation of Polyethylene Glycol and Polyethylene Glycolated Protein Using Ammonium Ferrioxalate", pp. 224-231, <u>Analytical Biochemistry</u> , 237, (1996).	
		Cheng et al., "Accelerated Clearance of Polyethylene Glycol-Modified Proteins by Anti-Polyethylene Glycol IgM", pp. 520-528, <u>Bioconjugate Chemistry</u> , Vol. 10, No. 3, 1999.	
		Cheng et al., "Efficient Clearance of Poly(ethylene glycol)-Modified Immunoenzyme with Anti PEG Monoclonal Antibody for Prodrug Cancer Therapy", pp. 258-266, <u>Bioconjugate Chemistry</u> , Vol. 11 No. 2 (2000)	
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		Ryan et al., "Separation and Quantitation of Polyethylene Glycols 400 and 3350 from Human Urine by High Performance Liquid Chromatography", pp. 350-351, <u>Journal of Pharmaceutical Sciences</u> , 351, Vol. 81, No. 4, April 1992)	

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		Sharma et al., "Inactivation and Clearance of an Anti-CEA Carboxypeptidase G2 Conjugate in Blood After Localization in a Xenograft Model", pp. 659-662, <i>British Journal of Cancer</i> , 61, (1990).	
		Stocks, et al., "A Fluorometric Assay of the Degree of Modification of Protein Primary Amines with Polyethylene Glycol", pp. 232-234, <i>Analytical Biochemistry</i> , 154, (1986).	

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LIST OF REFERENCES CITED BY APPLICANT

Atty Docket No.: 4910-2 Filing Date: March 07, 2000
Serial No.: 09/520,255 Group Art:
Applicant: Steve ROFFLER et al.

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U.S. PATENT DOCUMENTS

*Ex. Intls.		Document No.	Date	Name	Class	Subclass	Filing Date
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FOREIGN PATENT DOCUMENTS

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OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

mg	AE		Klibanov et al., "Blood Clearance of Radiolabeled Antibody: Enhancement by Lactosamination and Treatment with Biotin-Avidin or Anti-Mouse IgG Antibodies", pp. 1951-1956, The Journal of Nuclear Medicine, Vol. 29, No. 12, Dec. 1988
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✓	AP		Nag et al., "A colorimetric Assay for Estimation of Polyethylene Glycol and Polyethylene Glycolated Protein Using Ammonium Ferrothiocyanate", pp. 224-231, Analytical Biochemistry 237, (1996)

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mg	AQ	Cheng et al., "Accelerated Clearance of Polyethylene Glycol-Modified Proteins by Anti-polyethylene Glycol IgM", pp. 520-528, Bioconjugate Chemistry, Vol 10, No. 3, <u>date missing</u>
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